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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/634,321	KOSITPRAPA, UNCHALEE	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7 and 20-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7 and 20-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 7, and 20-37 are pending. Applicant cancelled claims 2-6 and 8-19. Claims 1 and 20-21 were amended. Claims 22-37 are new. The claim amendments introduced a new limitation not present in the previously examiner claims, namely "wherein said HMG-CoA reductase inhibitor is lovastatin." Receipt and consideration of Applicant's amended claims and remarks/arguments submitted on September 18, 2006 is acknowledged.

Specification

The objection to the specification for the improper use of the trademarks AVICEL® (pg. 13 Table; pg. 14 Table; pg. 15, lines 6 and 11; pg. 16 Table; pg. 18 Table and line 14; pg. 21 Table and line 16; pg. 22 Table; pg. 23 Table and line 7; and pg. 24 Table and line 9), PLASDONE® (pg 14 Table; pg 19 Table; pg 21 Table; Tables on pages 22-23), and EUDRAGIT® (Tables on pages 13-15, 18, 20, and 23; pg. 11, line 1; pg. 14, line 15; pg. 15, line 14; and pg. 17, line 15) **is maintained**, because said trademarks have not been appropriately capitalized.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claim 9 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is moot,** because said claim has been cancelled.

Claims 32, 34, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32, 34, and 36 are vague and indefinite because these depend from claim 1, which requires that the composition comprise "at least one water-soluble binder and at least one water-insoluble binder." The cited claims claim a range for the total amount of binder that includes "0%" binder. No binder is inconsistent with parent claims 1, 20, and 21, which do not allow for compositions comprising zero binder. It is noted that the only required components of the composition of claims 32, 34, and 36 is an active agent (i.e. either an anti-diabetic or a HMG-CoA reductase inhibitor), because the other components are optionally present and binders are not required (i.e. present in an amount of 0% by weight). Appropriate correction is required.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-3, 6, 7, and 20-22 under 35 U.S.C. 102(b) as being anticipated by Morella et al. (WO 94/05262) **is withdrawn** per Applicants' amendments limiting the active to anti-diabetics and HMG-CoA reductase inhibitors. The rejection of claim 3 **is moot**, because said claim was cancelled.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32, 34, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Kanios et al. (U.S. Patent 5,719,197).

Applicants claim an oral controlled release pharmaceutical composition comprising (1) a therapeutically effective amount of at least one pharmaceutically active ingredient; (2) an optional surfactant; (3) an optional alkaline agent; and (4) at least one water soluble binder and at least one water insoluble binder, wherein the active ingredient is selected from the group consisting of anti-diabetics, HMG-CoA reductase inhibitors, or mixtures thereof and wherein said water-soluble binder and said water-insoluble binder comprise from 0 to about 10 wt% of the composition. In other words, the only required component of the claimed composition is a pharmaceutically active ingredient that is selected from the group consisting of anti-diabetics and HMG-CoA reductase inhibitors.

Kanios discloses that known **anti-diabetic drugs include sulfonylurea derivatives, including glipizide** (col. 19, lines 13-24); anti-hyperlipoproteinemic drugs include **HMG-CoA reductase inhibitors, such as lovastatin**, pravastatin, and simvastatin (col. 20, lines 40-41); and that these drugs are suitable for incorporation into compositions comprising pharmaceutical active agents intended for topical administration (title, abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 8-9 under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (WO 94/05262) **is moot**, because said claims have been cancelled.

The rejection of claims 11-14 and 17-19 under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (94/05262) in view of Kanios et al. (U.S. Patent No. 5,719,197) ("Kanios") **is moot** because said claims have been cancelled.

Claims 1, 7, and 20-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (94/05262) in view of Kanios et al. (U.S. Patent No. 5,719,197) ("Kanios") for the reasons of record set forth on pages 4-6 (Morella) and 7-8 (Kanios) and further articulated herein below. Relevant additional teachings from Morella are set forth below for Applicants' convenience.

Applicant Claims

Applicants claim an oral controlled release pharmaceutical composition comprising (1) a therapeutically effective amount of at least one pharmaceutically active ingredient; (2) an optional surfactant; (3) an optional alkaline agent; and (4) at least one water soluble binder and at least one water insoluble binder, wherein the active ingredient is selected from the group consisting of anti-diabetics, HMG-CoA reductase inhibitors, or mixtures thereof.

NOTE: The Applicant has implicitly stated on the record in the response to the restriction requirement mailed on September 22, 2005 that the drugs incorporated into an oral controlled release pharmaceutical composition are not patentably distinct: "Applicant disagrees with the characterization that the species disclosed are patentably distinct (see page 2 of Applicants' response, labeled as "Transmittal Letter" in IFW).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Morella and Kanios have been set forth on pages 4-6 (Morella) and 7-8 (Kanios) of the previous office action mailed on April 13, 2006. Additional relevant teachings are set forth herein. Morella teaches that it is known in the prior art to be desirable in the treatment of diseases for prolonged periods to provide active pharmaceutical ingredients in a sustained release form, because this (1) minimizes the frequency of required administrations; (2) increases the reliability of treatment by decreasing the frequency of irregular administration; (3) results in a more nearly constant therapeutic level of active ingredient in the body; (4) minimizes the risk of drug blood levels not being within required therapeutic indices; and (5) avoids blood level peaks of drug usually found after intake of rapid release forms (pg. 1, lines 7-23). Morella teaches that nifedipine may be present in the controlled release formulations **in an amount preferably ranging from 5-70% by weight** (pg. 8, line 28). Kanios teaches that known anti-diabetic drugs include sulfonylurea derivatives, including glipizide (col. 19, lines 13-24) and that anti-hyperlipoproteinemic drugs include **HMG-CoA reductase inhibitors, such as lovastatin**, pravastatin, and simvastatin (col. 20, lines 40-41).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Morella lacks the teaching of drugs that are anti-diabetics (e.g. glipizide) and HMG-CoA reductase inhibitors (e.g. lovastatin). This deficiency is cured by the teachings of Kanios.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Morella and Kanios, because Morella teaches controlled release formulations in which the core comprises an active agent and Kanios teaches a plethora of pharmaceutical active agents. Furthermore, it would have been obvious to substitute nifedipine for an anti-diabetic or a HMG-CoA reductase inhibitor, as evidenced by Applicants' admission in the response to the restriction requirement mailed on September 22, 2005, "Applicant disagrees with the characterization that the species disclosed are patentably distinct." In other words, there is no patentable distinction between the active agents included in a controlled release formulation, and an ordinary skilled artisan would have been motivated to rely upon the teachings of Kanios as a convenient concise listing of a wide variety of pharmaceutical active agents, which in the course of routine experimentation and optimization, would be substituted for the actives taught by Morella to obtain controlled release formulations of these other active agents.

Nonetheless, notwithstanding Applicants' admission that the drugs in a controlled release formulation are not patentably distinct, an ordinary skilled artisan would have been motivated to

modify the sustained release formulations of Morella to comprise anti-diabetic or HMG-CoA reductase inhibitors because these drugs are used to treat chronic diseases (i.e. diabetes and hyperlipidemia (i.e. high cholesterol)), which requires prolonged treatment. A person of ordinary skill in the art would also have been motivated to utilize Morella's' teachings as the basis of controlled release formulations comprising either anti-diabetic drugs or HMG-CoA reductase inhibitors, because the advantages of controlled release formulations over rapid release formulations (i.e. typical formulations) are especially desirable in treatments requiring prolonged drug administration. For the reasons discussed above, a person of ordinary skill in the art would have had a reasonable expectation of success upon combination of the teachings of Morella and Kanios.

The rejection of claims 4 and 8-10 under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (WO 94/05262) in view of Curatolo et al. (U.S. Patent No. 6,068,859) ("Curatolo") **is moot**, because said claims have been cancelled.

The rejection of claims 4-5, 11-13, 15, 16, and 18-19 under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (WO 94/05262) in view of Acharya (U.S. Patent No. 5,686,094) ("Acharya") **is moot**, because said claims have been cancelled.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4, 7, and 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 7-9 of U.S. Patent No. 6,174,548 (USPN '548) in view of Morella (WO 94/05262) and view of Kanios et al. (U.S. Patent No. 5,719,197) ("Kanios") for the reasons of record set forth on pages 13-14 of the previous office action mailed on April 13, 2006 and further articulated herein below. Applicants' attention is also pointed to Kanios' teachings of HMG-CoA reductase inhibitors, such as lovastatin (col. 20, lines 40-42).

Response to Arguments

Applicant's arguments filed September 18, 2006 have been fully considered but they are not persuasive. Applicants have argued that this rejection is no longer proper because the drugs in the claimed compositions have been limited to only anti-diabetics and HMG-CoA reductase inhibitors. This is found unpersuasive in further view of the teaching of Morella and Kanios. The teachings of Morella and Kanios were set forth on pages 4-6 and 7-8, respectively, of the previous office action mailed on April 13, 2006. It is noted that in addition to anti-diabetics (e.g. glipizide; col. 19, line 18) Kanios teaches HMG-CoA reductase inhibitors, such as lovastatin

(col. 20, lines 40-42). Furthermore, Applicants arguments also are found unpersuasive because, in the response to the restriction requirement mailed on September 22, 2005, Applicant stated, "Applicant disagrees with the characterization that the species disclosed are patentably distinct." In other words, Applicants implicitly admitted that there is no patentable distinction between the drugs incorporated into a controlled release formulation, and thus an ordinary skilled artisan would have been motivated to rely upon the teachings of Kanios as a convenient concise listing of a wide variety of pharmaceutical active agents, which in the course of routine experimentation and optimization, would be substituted for the actives taught by Morella to obtain controlled release formulations of these other active agents.

Nonetheless, notwithstanding Applicants' admission that the drugs in a controlled release formulation are not patentably distinct, an ordinary skilled artisan would have been motivated to modify the sustained release formulations of Morella to comprise anti-diabetic drugs or HMG-CoA reductase inhibitors because these drugs are used to treat chronic diseases (i.e. diabetes and hyperlipidemia (i.e. high cholesterol)), said treatment requiring prolonged repeated treatment over the course of several months or more. A person of ordinary skill in the art would also have been motivated to utilize Morella's' teachings as the basis of controlled release formulations comprising either anti-diabetic drugs or HMG-CoA reductase inhibitors, because the advantages of controlled release formulations over rapid release formulations (i.e. typical formulations) are especially desirable in treatments requiring prolonged drug administration, such as in the treatment of diabetes or hyperlipidemia (i.e. high cholesterol).

The rejection of claims 4-5 and 8-10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 5-11, 16, and 18-19 of U.S. Patent No. 6,602,522 (USPN '522) **is moot** because said claims have been cancelled.

Claims 1, 6-7, 21, and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 5-11, 16, and 18-19 of U.S. Patent No. 6,602,522 (USPN '522) in view of Kanios et al. (U.S. Patent No. 5,719,197) ("Kanios") for the reasons of record set forth on pages 14-15 of the previous office action mailed on April 13, 2006 and further articulated herein below. Applicants' attention is also pointed to Kanios' teachings of HMG-CoA reductase inhibitors, such as lovastatin (col. 20, lines 40-42).

Response to Arguments

Applicant's arguments filed September 18, 2006 have been fully considered but they are not persuasive. Applicants have argued that this rejection is no longer proper because the drugs in the claimed compositions have been limited to only anti-diabetics and HMG-CoA reductase inhibitors. This is found unpersuasive in further view of the teaching of Kanios. The teachings of Kanios were set forth on pages 7-8 of the previous office action mailed on April 13, 2006. It is noted that in addition to anti-diabetics (e.g. glipizide; col. 19, line 18) Kanios teaches HMG-CoA reductase inhibitors, such as lovastatin (col. 20, lines 40-42). Furthermore, Applicants arguments also are found unpersuasive because, in the response to the restriction requirement mailed on September 22, 2005, Applicant stated, "Applicant disagrees with the characterization that the species disclosed are patentably distinct." In other words, Applicants implicitly admitted

that there is no patentable distinction between the drugs incorporated into a controlled release formulation, and thus an ordinary skilled artisan would have been motivated to rely upon the teachings of Kanios as a convenient concise listing of a wide variety of pharmaceutical active agents, which in the course of routine experimentation and optimization, would be substituted for the actives taught by Morella to obtain controlled release formulations of these other active agents.

The rejection of claims 3 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 7-9 of U.S. Patent No. 6,733,778 (USPN '778) in view of Morella (WO 94/05262) **is moot**, because said claim has been cancelled.

Claims 1-2, 5-11, and 13-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 7-9 of U.S. Patent No. 6,733,778 (USPN '778) in view of Morella (WO 94/05262) and Kanios et al. (U.S. Patent No. 5,719,197) ("Kanios") for the reasons of record set forth on page 15 of the previous office action mailed on April 13, 2006 and further articulated herein below. Applicants' attention is also pointed to Kanios' teachings of HMG-CoA reductase inhibitors, such as lovastatin (col. 20, lines 40-42).

Response to Arguments

Applicant's arguments filed September 18, 2006 have been fully considered but they are not persuasive. Applicants have argued that this rejection is no longer proper because the drugs in the claimed compositions have been limited to only anti-diabetics and HMG-CoA reductase

inhibitors. This is found unpersuasive in further view of the teaching of Kanios. The teachings of Kanios were set forth on pages 7-8 of the previous office action mailed on April 13, 2006. It is noted that in addition to anti-diabetics (e.g. glipizide; col. 19, line 18) Kanios teaches HMG-CoA reductase inhibitors, such as lovastatin (col. 20, lines 40-42). Furthermore, Applicants arguments also are found unpersuasive because, in the response to the restriction requirement mailed on September 22, 2005, Applicant stated, "Applicant disagrees with the characterization that the species disclosed are patentably distinct." In other words, Applicants implicitly admitted that there is no patentable distinction between the drugs incorporated into a controlled release formulation, and thus an ordinary skilled artisan would have been motivated to rely upon the teachings of Kanios as a convenient concise listing of a wide variety of pharmaceutical active agents, which in the course of routine experimentation and optimization, would be substituted for the actives taught by Morella to obtain controlled release formulations of these other active agents.

Other Matter

The Examiner respectfully requests that Applicants utilize proper Markush group language to indicate the group of drugs suitable for incorporation in Applicants' invented composition.

Conclusion

Claims 1, 7, and 20-37 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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